IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

APOTEX INC.,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and IPR PHARMACEUTICALS, INC.,

Defendants.

Civil Action No.: 8:08-cv-213-JSM-TGW

DISPOSITIVE MOTION

DEFENDANTS' MOTION TO DISMISS COMPLAINT WITH PREJUDICE AND SUPPORTING MEMORANDUM OF LAW

Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and IPR Pharmaceuticals, Inc. (collectively "AstraZeneca") hereby move to dismiss Apotex Inc.'s Complaint with prejudice for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

I. THE NATURE AND STAGE OF THE PROCEEDING

Apotex Inc. ("Apotex") has sued AstraZeneca for a declaratory judgment of non-infringement of U.S. Patent No. 6,316,460 ("the '460 patent"). That patent claims a drug formulation for AstraZeneca's highly successful, cholesterol-lowering drug, CRESTOR®. This action results from Apotex filing Abbreviated New Drug Application ("ANDA") No. 79-145 with the United States Food and Drug Administration ("FDA") and certifying that it intends to market generic versions of AstraZeneca's CRESTOR® products before expiration

of the '460 patent and U.S. Reissue Patent RE37,314 ("the '314 patent"), a related patent that covers CRESTOR®'s active ingredient, rosuvastatin calcium.

Apotex is one of seven generic drug manufacturers to so challenge the '314 and '460 patents. In an effort to resolve the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions in the District of Delaware on December 11, 2007.[1] The Complaint in each action alleges infringement of only the '314 patent. Rather than answer the Complaint, Apotex moved to dismiss the Delaware action for lack of jurisdiction and simultaneously initiated this action in the Middle District of Florida. Significantly, Apotex's declaratory judgment action only involves the '460 patent. Because AstraZeneca has given Apotex a covenant not to sue under the '460 patent, AstraZeneca seeks to dismiss Apotex's Complaint with prejudice.

II. SUMMARY OF ARGUMENT

AstraZeneca gave Apotex a covenant not to sue under the '460 patent. As federal courts have repeatedly held, a covenant not to sue divests the court of subject matter jurisdiction, renders moot the declaratory judgment claim regarding patent infringement and validity, and eliminates any alleged Article III standing relating to the patent claim.

III. STATEMENT OF FACTS

This case concerns AstraZeneca's CRESTOR® pharmaceutical product, and Apotex's efforts to sell a generic version of CRESTOR® before the '460 patent expires. On November 5, 2007, Apotex notified AstraZeneca of its ANDA No. 79-145, seeking FDA approval to

[1] Civil Action Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811. Apotex Inc. and its U.S. subsidiary, Apotex Corp., are defendants in Civil Action 07-809.

engage in the manufacture, importation, use or sale of generic rosuvastatin calcium before the '460 patent expires. Subsequently, on December 4, 2007, Apotex notified AstraZeneca that it had amended the ANDA, certifying its intention to sell generic rosuvastatin calcium before expiration of the '314 patent, as well. In response, AstraZeneca filed suit against Apotex and its subsidiary, Apotex Corp., in the District of Delaware, but only on the '314 patent.

Apotex moved to dismiss AstraZeneca's Delaware complaint and simultaneously filed this action, seeking a declaratory judgment that its proposed generic rosuvastatin calcium product will not infringe the '460 patent. (Dkt. #1, ¶¶ 21-23.) On March 25, 2008, AstraZeneca gave Apotex a covenant not to sue on the '460 patent. (Ex. A.) Because the covenant not to sue eliminates any potential case or controversy related to the '460 patent, AstraZeneca now moves to dismiss Apotex's Complaint with prejudice for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1).

IV. ARGUMENT

To establish jurisdiction under the Declaratory Judgment Act, Apotex bears the burden of proving that the facts alleged "under all the circumstances show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007). Under this standard, AstraZeneca's covenant not to sue Apotex for infringement of the '460 patent dictates dismissal of all the claims in Apotex's Complaint for at least three reasons. First, it divests this Court of subject matter jurisdiction over Apotex's Complaint, because it conclusively resolves any potential case or controversy. Second, without a case or controversy, Apotex's claims become hypothetical, advisory, and, thus, improper. Third, the covenant eliminates any Article III standing, because Apotex

cannot identify any requisite injury in fact. *See Pfizer, Inc. v. Ranbaxy Labs. Ltd,* 525 F. Supp. 2d 680, 684 (D. Del. Nov. 29, 2007); *Merck & Co., Inc. v. Apotex, Inc.,* 488 F. Supp. 2d 418, 424 (D. Del. May 21, 2007) (Apotex counterclaim dismissed because, "it is well-established that a trial court may be divested or deprived of subject matter jurisdiction over a particular patent claim if the patentee covenants not to assert an infringement claim against a putative infringer."); *Janssen Pharmaceuticals, N.V. v. Apotex, Inc.,* 2007 WL 3014702, at *2 (D.N.J. October 11, 2007) (Apotex counterclaims dismissed, "because there is no case or controversy surrounding the patents Defendant alleges are in issue" where covenant not to sue was given.).

In both *Janssen* and *Merck*, Apotex opposed motions to dismiss its declaratory judgment counterclaims, asserting that the Federal Circuit's recent decision in *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.,* 482 F.3d 1330 (Fed. Cir. 2007) prevented dismissal. Both courts, however, ruled against Apotex because, unlike the situation in *Novartis*, the patentees in *Janssen* and *Merck*, as here, had given Apotex a covenant not to sue. *Janssen*, 2007 WL 3014702, at *3 ("the present action is distinguished from *Novartis* as [patentee] point[s] out, there was no covenant not to sue in *Novartis*." (citation omitted)); *Merck*, 488 F. Supp. 2d at 423 ("A significant distinction between the scenario in *Teva v. Novartis* and the case here is that Novartis had declined to give Teva a covenant not to sue."). Indeed, the *Janssen* court relied on *Novartis* to rule that "a covenant not to sue usurps the opportunity to bring an action for declaratory judgment." *Janssen,* 2007 WL 3014702 at *3.

In another recent case, the patentee had brought suit against a generic drug manufacturer on two patents. *Pfizer v. Ranbaxy,* 525 F. Supp. 2d 680, 683-684. In response,

the generic drug manufacturer filed, *inter alia*, counterclaims seeking declaratory relief on a third patent that the patentee had not asserted and on which the patentee had given a covenant not to sue. Similar to the situation here, the patentee "contend[ed] that there [was] no justiciable case or controversy between the parties and no declaratory judgment jurisdiction with respect to these counterclaims based on the covenant not to sue." *Id.* at 685. The court agreed, ruling that a covenant not to sue conclusively divested the court of subject matter jurisdiction. *Id.* at 686 (citing *Merck,* 488 F. Supp. at 423-425); *see also id.* at 687 (advisory opinions are "wholly inconsistent with the most basic precepts of jurisdictional jurisprudence."). The court also held that the covenant not to sue removed any Article III standing, because the Defendant had not suffered any requisite injury in fact. *Id.*

The recent decision by the Federal Circuit in *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.,* 2008 U.S. App. LEXIS 6383 (Fed. Cir. April 1, 2008), should not affect the outcome of this motion, because it is both legally and factually inapposite to the current dispute. First, and most importantly, the ANDA filer in *Caraco* was not the first ANDA filer, which in that case acted as an impediment to market entry of its generic product. In the present case, Apotex is considered a first filer,[2] thereby freeing it of the restraints on market entry identified in the *Caraco* decision.[3]

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[2] AstraZeneca has reason to believe that Apotex Inc. and Apotex Corp. are considered first-filers, because under the rules, every party that files a substantially complete ANDA on the first day allowed under law is considered a first filer. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

[3] The *Caraco* decision was grand-fathered into and thus governed by old Hatch-Waxman rules, which, in part, tied market entry for subsequent ANDA filers to the first filer's market entry. Amendments to the Hatch-Waxman Act in 2003, which govern this case, have resolved this issue by including safeguards for subsequent ANDA filers, thereby rendering the

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Under the regulatory scheme created by the Hatch Waxman Act, generic drug manufacturers are given incentives to challenge patents covering branded drug products. One of those incentives is the granting of a 180-day period of market exclusivity for the first generic drug manufacturer to file an ANDA. Subsequent ANDA filers must wait until the first filer's 180-day exclusivity period ends before entering the market. According to the Federal Circuit's interpretation of the old rules in *Caraco*, the 180-day period is "triggered" when either the first filer enters the marketplace or any filer obtains a judgment successfully challenging the relevant Orange Book listed patents. *Id.* at 5. The Court also interpreted the old rules to allow for second filers to trigger the 180-day period by obtaining a judgment that all of the Orange Book listed patents are invalid, unenforceable, or not infringed. *Id.* at 6-7.

In *Caraco*, the first ANDA filer was held to infringe one of the Orange Book listed patents at issue. As a result, it was precluded from entering the market and triggering the 180-day exclusivity period. Additionally, the patent owner gave the subsequent ANDA filer a covenant not to sue on the second of only two Orange Book listed patents, preventing the second filer from obtaining a judgment on all of the Orange Book listed patents. Under those circumstances, the Federal Circuit ruled that the covenant not to sue did not eliminate the case or controversy on the patents, because the second ANDA filer was in fact injured—it could not enter the market because the first ANDA filer could not trigger the 180-day exclusivity

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ANDA filer's predicament in *Caraco* altogether moot. *See* 21 U.S.C. § 355(j)(5)(D). As the Court explained in *Caraco*, "the…amendments to the provisions governing the commencement of 180-day exclusivity period are inapplicable to this case." *Caraco,* 2008 U.S. App. LEXIS at n.2.

period, and without the ability to obtain a judgment on both patents, the second ANDA filer could not independently trigger that exclusivity period.

Here, there is no such injury-in-fact. The covenant at issue will not prevent Apotex, a first filer, from entering the market. If anything, it removes a potential barrier from Apotex's market entry if Apotex is successful in challenging the '314 patent in the Delaware action. Accordingly, the *Caraco* decision does not apply here, and AstraZeneca's covenant not to sue eliminates the case or controversy over the '460 patent.

Just as the covenants not to sue in similar situations were dispositive of the *Janssen, Merck*, and *Pfizer* cases, the covenant not to sue that AstraZeneca gave Apotex is dispositive of this case. As a result of the covenant, the Court is divested of subject matter jurisdiction over Apotex's declaratory judgment action, Apotex's declaratory judgment claim is rendered moot, and Apotex lacks standing to maintain this suit.

V. CONCLUSION

For the forgoing reasons, AstraZeneca respectfully requests that the Court dismiss Apotex's Complaint with prejudice for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1).

Dated: April 10, 2008

Respectfully submitted,

s/Lara J. Tibbals
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 10, 2008, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to Lee Fugate and Nathan M. Berman, Zuckerman Spaeder LLP, 101 E. Kennedy Boulevard, Suite 1200, Tampa, Florida 33602 and to Robert B. Breisblatt, J. Aron Carnahan and Laurie A. Haynie, Welsh & Katz, Ltd., 120 S. Riverside Plaza, 22nd Floor, Chicago, Illinois 60606.

s/Lara J. Tibbals
Attorney

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March 25, 2008

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Apotex v. AstraZeneca, C.A No. 8:08-cv-213-JSM-TGW

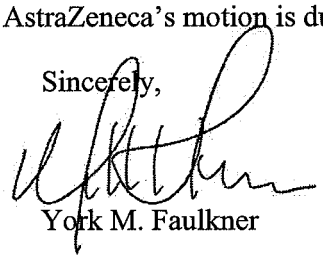
Dear Counsel:

We write regarding the above-referenced action that Apotex, Inc. filed in the Middle District of Florida, seeking declaratory relief that the product described in ANDA No. 79-145 does not infringe U.S. Patent No. 6,316,460 (the '460 patent). AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and AstraZeneca AB (collectively "AstraZeneca") covenant not to assert infringement of the '460 patent on the following conditions. Specifically, provided that the formulation of the proposed product as described in the excerpts given to AstraZeneca from ANDA No. 79-145 does not change, AstraZeneca represents that it will not sue Apotex Inc. or Apotex Corp. for any infringement of any claim of the '460 patent concerning the rosuvastatin calcium product for which ANDA No. 79-145 currently seeks FDA approval.

Exhibit "A"

This commitment eliminates any case or controversy alleged in C.A No. 8:08-cv-213. Accordingly, AstraZeneca will move to dismiss Apotex's Inc.'s Complaint for Declaratory Relief rather than answer it. Nevertheless, we prefer to avoid unnecessary motion practice and are open to discussing this further with the objective of obtaining consent to the dismissal of this action before Apotex Inc.'s opposition to AstraZeneca's motion is due.

Sincerely,



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